Dartmouth-Hitchcock Medical Center

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August 28, 1999

Dockets Management Branch (HFA-305)
Food and Drug Adinistration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 98N-0581
Proposed Rule: Requiremetns for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents
21 CFR Parts 607, 610, 640 and 660
August 19, 1999

Dear Sirs:

I am writing to object strongly to the provisions of the proposed rule requiring testing of all autologous donations. The logic behind this provision is faulty, and the effect of the rule will be to reduce the availability and usage of preoperative autologous donations, an undesirable outcome.

The agency states that one reason for requiring infectious disease testing of all autologous units is that there have been (rare) reports of their being transfused to someone other than the donor. However, the proposed testing requirement will not alleviate this concern nor consider allowances for systems that do provide failproof systems to prevent mistransfusion.

Under current requirements, units collected by a blood center are tested for infectious disease markers since the transfusion will be at another facility. When these autologous units are found to be marker-positive, hospitals almost always request that they be sent to the hospital for storage and transfusion anyway.. The presence of a special label on these units is still no guarantee that will end up in the vein of the donor. Furthermore, as denial of the "right" to donate preoperatively to a marker-positive donor may place the collection agency in violation of the Americans with Disability Act, or refusal to accept such units may place the hospital in violation of the Act, marker-positive units will continue to exist in transfusion service inventories. If concerned about the dangers of mistransfusion (which kills an order of magnitude more recipients than all transfusion-transmitted infectious diseases annually), the agency should focus on this problem for all transfusions.

Requiring testing of all autologous units will serve to restrict the availability of autologous collection services. This will particularly true in rural areas, such as the one where we are located. Small community hospitals located in rural areas offer patients ready access to

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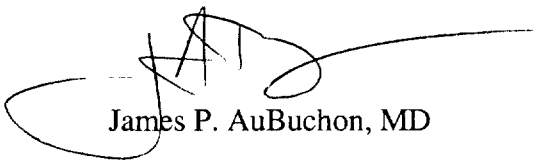
autologous collection services. Testing requirements will serve to push these hospitals to close their autologous collection operations since they do not have access to testing services. (Most hospitals do not perform all FDA-required tests.) Contracting out the testing services will be complex and costly, with which neither complication small hospitals have the resources to contend. Since the nearest blood center may be several hours away (and transportation in rural areas, particularly for senior citizens, is almost non-existent), the effect of the proposed requirement would be to deny an already underserved segment of the population access to an important health service.

Therefore, I strongly urge that the FDA continue to consider the collection and transfusion of autologous blood within an institution the practice of medicine and forego requiring infectious disease testing of such units.

Thank you.

Sincerely,



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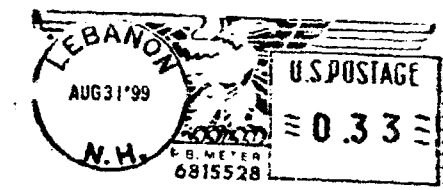

DOCKETS MANAGEMENT BRANCH (HFA-305)
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DOCKET No. 98N-0551

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